UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,453	11/28/2003	James C. Peacock III	53233-00007	9909

48423 7590 04/03/2007

KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP
ATTN: C. RACHAL WINGER
925 FOURTH AVE
SUITE 2900
SEATTLE, WA 98104-1158

EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	**PAPER NUMBER**
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,453	PEACOCK, JAMES C.	
	Examiner	Art Unit	
	Katherine M. Dowe	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/2005 and 7/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-27 and 29-37 and 39-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Gertner et al. (US 2003/0060873). Regarding claims 1, 2, 6, 17, 18, and 44-46, Gertner et al. disclose a stent (Fig 1, element 12) comprising a scaffold constructed from a first material and with a porous outer surface comprising a coating (10) with pores (14). The stent is coated with a metallic matrix, which has pores containing a composite material comprising a plurality of particles of a bioactive agent stored in an erodible polymer (para 0011, 0050).

Regarding claims 3-5, Gertner et al. disclose the outer diameter of the particles is less than about 1 micron (para 0050).

Regarding claims 7-10, Gertner et al. disclose the inner diameter of the pores is substantially equivalent to the outer diameter of the particles since the bioactive material particles are co-deposited along with the metal (para 0052) and thus the inner diameter of the pores is less than about 1 micron (para 0050; 0065).

Regarding claim 11, Gertner et al. disclose the porous outer surface may comprise a material that is inherently porous (para 0044).

Regarding claims 12-15, Gertner et al. disclose the porous outer surface may comprise a material that is not inherently porous, and the pores are etched into the material (para 0044).

Regarding claim 16, Gertner et al. disclose the porous outer surface may comprise a sintered material (para 0009).

Regarding claims 19-21, Gertner et al. disclose the metallic matrix of the coating comprises is electrolessly electrochemically deposited (para 0048) and thus comprises a metal and a reducing agent of the metal (para 0036, 0057).

Regarding claims 22-23 and 26-27, Gertner et al. disclose the metal may comprise nickel or cobalt and the reducing agent may comprise phosphorus (para 0056, 0064).

Regarding claims 24 and 25, Gertner et al. disclose the first material may comprise stainless steel alloy or nitinol (para 0044).

Regarding claims 29-33, Gertner et al. disclose a second material may be formed between the first material and the coating material and a third material may be formed between the second material and the coating material since a plurality of layers may be formed with coating layers comprising bioactive material between metallic layers (para 0063). The second material may be electroplated metal such as nickel (para 0029, 0036, 0064), the third material may be a layer of electrolessly electrochemically deposited composite with metal and a reducing agent of the metal (0056-0058), and the

coating may be another layer of electrolessly electrochemically deposited composite with metal and reducing agent of the metal with the composite material (0051).

Regarding claims 34-37 and 39, Gertner et al. disclose the bioactive agent may be an anti-restenosis agent, an anti-inflammatory agent, an anti-proliferative agent, or a growth factor (para 0007, 0027, 0028).

Regarding claims 40-43, Gertner et al. disclose that by using an electroless deposition process, the percentage of bioactive material is controllable and thus the ratio of bioactive material to bioerodable material may be at least about 1.5:1 by adjusting the pH, temperature, and the constituents of the deposition bath accordingly (para 0068).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gertner et al. (US 2003/0060873), as applied to claim 26 above, in view of Ding et al. (US 6,120,536). Gertner et al. disclose the invention substantially as claimed including a stent (Fig 1, element 12) comprising a scaffold constructed from a first material and with a porous outer surface comprising a coating (10) with pores (14). The stent is coated with a metallic matrix, which has pores containing a composite material comprising a plurality of particles of a bioactive agent stored in an erodible polymer (para 0011, 0050). The metallic matrix of the coating comprises is electrolessly electrochemically deposited (para 0048) and thus comprises a metal and a reducing agent of the metal (para 0036, 0057), where the metal may comprise nickel or cobalt and the reducing agent may comprise phosphorus (para 0056, 0064). However, Gertner et al. does not disclose the stent (first material) may comprise cobalt chromium alloy. Ding et al. disclose a similar stent structure that may be composed of a variety of materials including a cobalt chromium alloy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Gertner et al. such that the stent was composed of a cobalt chromium alloy. Thus, manufacturing costs could be minimized by introducing more options for available materials and the marketability of the device would increase by having more available material options such that patients allergic to one material could use another for example.

6. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gertner et al. (US 2003/0060873), as applied to claim 1 above, in view of Wang et al. (US

2007/0037739). Gertner et al. disclose the invention substantially as claimed including a stent (Fig 1, element 12) comprising a scaffold constructed from a first material and with a porous outer surface comprising a coating (10) with pores (14). The stent is coated with a metallic matrix, which has pores containing a composite material comprising a plurality of particles of a bioactive agent stored in an erodible polymer (para 0011, 0050). Furthermore, the bioactive agent may be an anti-restenosis agent, an anti-inflammatory agent, or an anti-proliferative agent (para 0007, 0027, 0028). However, Gertner et al. does not disclose the bioactive agent may comprise des-aspartate angiotensin 1. Wang et al. disclose compounds useful in coating stents to treat restenosis including des-aspartate angiotensin 1 (para 0040, 0253-0261) which has been shown to substantially inhibit smooth muscle cell proliferation and drastically reduce restenosis (para 0261). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Gertner et al. such that the bioactive compound may also comprise des-aspartate angiotensin 1. Thus, the marketability of the device would increase and the stent may be more effective by effectively reducing restenosis.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chandresekara et al. (US 2005/0251248), Johnson (US 2001/0029660), Crotty et al. (US 6,837,923), Chiba et al. (US 6,273,943), and Lye et al. (US 2004/0148015).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kmd
March 30, 2007

MJ Hayes

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER